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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,854	03/12/2004	Alexander P. Dorr	UCAL-296	2176
24353 7590 09/21/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER PARKIN, JEFFREY S	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,854	Applicant(s) DORR ET AL.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-41 is/are pending in the application.
- 4a) Of the above claim(s) 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-18 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 10/799,854
Applicants: Dorr, A. P., et al.

Docket No.: UCAL-296
Filing Date: 03/12/2004

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 27 June, 2007, wherein claims 1-6 were canceled without prejudice or disclaimer and new claims 29-41 introduced. Claims 19-28 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 7-18 and 129-41 are currently under examination.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The previous rejection of claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Deng et al. (2000), is moot in view of the cancellation of these claims.

The previous rejection of claims 1-3 under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(b) as being

anticipated by Mujtaba et al. (2002), is moot in view of the cancellation of these claims.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The previous rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Wildey et al. (1988), is moot in view of the cancellation of these claims.

The previous rejection of claims 6-18 under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Wildey et al. (1988) and Gu et al. (2002), is moot in view of the cancellation of claim 6 and the grounds for rejection set forth below.

The previous rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over Mujtaba et al. (2002) in view of Wildey et al. (1988), is moot in view of the cancellation of these claims.

The previous rejection of claims 6-18 under 35 U.S.C. § 103(a) as being unpatentable over Mujtaba et al. (2002) in view of Wildey et al. (1988) and Gu et al. (2002), is moot in view of the cancellation of claim 6 or the new grounds of rejection set forth below.

Claims 7-10, 17, 18, 29, and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Vitellio et al. (2002) and Yusuhiko et al. (2003). Deng and colleagues disclose the presence of acetylated Tat and demonstrate its importance in the viral lifecycle. The authors demonstrate that Tat acetylation at K50 alters the phenotypic properties of the protein. Vitellio and associates provide immunogenic compositions comprising an adjuvant (e.g., ALUM) and pharmaceutically acceptable excipients. Yusuhiko and coworkers describe the preparation of anti-N-epsilon-acetyllysine antibodies and their usefulness in numerous assay formats to detect acetylated proteins. Therefore, it would have been *prima facie* obvious at the time of the invention to one of ordinary skill in the art to prepare immunological reagents, as described

by Vitellio et al. (2002), employing the Tat polypeptides of Deng et al. (2000). One of ordinary skill in the art would have been motivated to prepare said immunological reagents to aid in diagnostic and biochemical studies. A reasonable expectation of success was clearly present in the prior art as demonstrated by Yusuhiko et al. (2003).

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Vitellio et al. (2002) and Yusuhiko et al. (2003), as applied *supra*, and further in view of Kukien et al. (2000). These teachings do not disclose the various HIV-1 isolates encompassed by the sequences set forth in SEQ ID NO.: 4. However, Kukien and associates provide the complete nucleotide sequences of numerous HIV-1 isolates, including that encompassed by SEQ ID NO.: 4. Therefore, it would have been *prima facie* obvious at the time of the invention to one of ordinary skill in the art to prepare immunological reagents employing Tat polypeptides obtained from numerous isolates, since this would facilitate the detection and biochemical analysis of Tat in different clades.

Claims 12-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Vitellio et al. (2002) and Yusuhiko et al. (2003), as applied *supra*, and further in view of Rubinstein et al. (2002). Rubinstein and associates provide immunogenic compositions comprising polypeptides linked to a carrier (e.g., PPDs). Therefore, it would have been *prima facie* obvious at the time of the invention to one of ordinary skill in the art to conjugate or link Tat to a carrier as described by Rubinstein and associates since this would increase the immune response to Tat.

Claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Vitellio et al. (2002) and Yusuhiko et al. (2003), as applied *supra*, and further in view of Frankel et al. (1988). Frankel and colleagues demonstrate that wildtype Tat exists in a multimeric configuration. Therefore, it would have been *prima facie* obvious at the time of the invention to one of ordinary skill in the art to prepare immunological reagents comprising multimeric forms of Tat since this would reasonably be expected to mimic the native structure of Tat.

Claims 30-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deng et al. (2000) in view of Vitellio et al. (2002), Yusuhiko et al. (2003), and Kukien et al. (2000). The claims are directed toward multivalent immunogenic compositions comprising multiple copies of Tat. It would have been *prima facie* obvious at the time of the invention to one of ordinary skill in the art to prepare immunological reagents comprising multiple copies of Tat, particularly from different clades, since this would facilitate the generation of immunological reagents that would be useful for the detection of cross-clade variants.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

New Matter

Claims 34-36 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The claims reference Tat polypeptides comprising amino acids 1-45, 55-72, or both 1-45 and 55-72. Perusal of the disclosure fails to provide support for the claimed limitations.

Correspondence


Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent

related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

17 September, 2007